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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,890	06/30/2000	Gary L. Johnson	CPI-004DVCP3CN	1962
959	7590	05/18/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP.			BASI, NIRMAL SINGH	
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BOSTON, MA 02109			PAPER NUMBER	

1646

DATE MAILED: 05/18/2004

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/608,890

Applicant(s)

JOHNSON, GARY L.

Examiner

Nirmal S. Basi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-64 is/are pending in the application.
- 4a) Of the above claim(s) 59-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 06 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 8/6/02 has been entered. Response to Office communication dated 4/4/03 has been entered.
2. Applicant's election, without traverse, of Group II (Claims 53-64) on 8/6/02 (paper number 10), is acknowledged. Applicant's election with traverse of SEQ ID NO:4 on 4/4/03 (paper number 13, is acknowledged. The traversal is on the ground(s) that the search of the MEKK1 sequence set forth as SEQ ID NO:1-2 would be coextensive with any search of the MEKK1 sequence set forth as SEQ ID NOs: 3-4. Applicant's arguments have been fully considered and found persuasive in part. The methods of Group II pertaining to the use of the polypeptides of SEQ ID NOs: 2 and 4 will be examined. Further Applicant traverses restriction of the polypeptides of SEQ ID NOs:6, 8, 10, 12 and 14, based on sequence structural and functional properties. Applicant's arguments, pertaining to the polypeptides of SEQ ID NOs:6, 8, 10, 12 and 14, encoded by the polynucleotides of SEQ ID NOs 5, 7, 9, 11 and 13, respectively, have been fully considered and not found persuasive. The polypeptides of SEQ ID NOs:6, 8, 10, 12 and 14 are significantly structurally and functionally dissimilar from the elected group, as exemplified by the grouping of the polypeptides into MEKK1, MEKK2, MEKK3 and MEKK4, in table 1 of the specification. A search for the polypeptides SEQ ID NOs:6, 8, 10, 12 and 14, encoded by the polynucleotides of SEQ ID NOs 5, 7, 9, 11 and 13, respectively, would not be co-extensive with the elected group, particularly with regard to the literature search, and would constitute a serious undue burden on the

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examiner. Amendment filed 8/6/02 cancelled claims 40-52. Claims 59-64 are withdrawn from further consideration as being drawn to methods requiring nucleic acid, said methods reading on gene therapy. The claimed invention, methods of using the polypeptide of SEQ ID NO: 2 and 4 do not require gene therapy and can be practiced by agents regulating MEKK protein activity. Claims 59-64 are objected to because they read on non-elected invention of the polypeptide of SEQ ID NO:2 and 4. Applicant must amend or withdraw the claims directed to non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Drawings, filed 8/06/02, are approved by the Examiner.

Objections

The disclosure is objected to because of the following informalities:

4. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 8, Applicant has written "Brief Description Of The Figures"

Appropriate correction is required.

5. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Further the relationship of said earlier applications must be disclosed as well as their current status. The priority information is not complete and must be updated. For example, there is no reference to US Application 08/628, 829, filed 4/5/1996, now patent number 6,333,170 etc

Appropriate correction is required.

6. The amendment filed 1/25/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (e.g., PPPSS trunc MEKK, PPPSS corresponding to amino acids 211 to 215 of SEQ ID NO:2).

The new matter has been added to page 8, line 18 and to page 94, line 3.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. Claims 59-64 are objected to because they pertain to the use of non-elected invention of the nucleic acid of SEQ ID NO:s: 1, 3, 5, 7, 9, 11, 13 and the polypeptide of SEQ ID NOs:6, 8, 10, 12 and 14. Applicant must amend or cancel claims reading on the non-elected group.

Sequence Rules Compliance

8. This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. There are numerous sequences contained in the specification, e.g. on pages 13, 45, 49, 69, 72, which have not been identified by SEQ ID NO:. Their corresponding SEQ ID NO must identify sequences present in the specification so as to comply with the sequence rules. Correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 53-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 53, 54, 55, and 56 are indefinite because the name MEKK protein does not provide any structural limitations and the metes and bounds of the claim cannot be determined. It is unclear what structure encompasses MEKK protein. It is unclear what structure encompasses nucleic acid encoding said MEKK protein. It is suggested, to overcome the rejection, MEKK protein and nucleic acid be identified by SEQ ID NO.

Claim 53 is indefinite because it is not clear what activity of the MEKK protein is regulated in the cell such that apoptosis of the cell is regulated, so as to allow the metes and bounds of the claim cannot be determined. It is suggested, to overcome the rejection, a specific activity be disclosed. Further it is not clear if "directly regulates" means the agent must bind to the MEKK to exert its effect or if regulation is by some other means.

Claims 54 and 55 are indefinite because it is not clear what activity of the kinase domain of MEKK protein is regulated, so as to allow the metes and bounds of the claim cannot be determined. Further, it is not clear which fragment of MEKK contains the

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critical structural feature of the invention to be classified as the kinase domain of MEKK protein. Also, it is not clear which fragment of MEKK contains the critical structural feature of the invention to be classified as the regulatory domain of MEKK protein. Although, the proteins of SEQ ID NOs 2 and 4 contain regions of the kinase domain and regulatory domain of MEKK protein, it is not clear at what amino acid said domains start and end, so as to allow the metes and bounds of the claim to be determined. It is suggested, to overcome the rejection, kinase domain and regulatory domain be identified by using SEQ ID NO: and specific amino acid positions in said SEQ ID NO: to indicate the start and end of said domains.

Claim 56 is indefinite because it is not clear which fragment of MEKK contains the critical structural feature of the invention to be classified as the kinase catalytic domain of MEKK protein. Although the proteins of SEQ ID NOs 2 and 4 contain regions of the kinase catalytic domain of MEKK protein it is not clear at what amino acid said domain starts and end, so as to allow the metes and bounds of the claim cannot be determined. It is suggested, to overcome the rejection, kinase catalytic domain be identified by using SEQ ID NO: and specific amino acid positions in said SEQ ID NO: used to indicate the start and end of said domain.

Claims 57 and 58 are rejected for depending upon an indefinite base (or intermediate) claim.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 53-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for regulating cell apoptosis comprising contacting the cell with an agent that binds to MEKK protein of SEQ ID NO:2 or 4 or the truncated MEKK disclosed in Example 15, wherein said agent regulate the ability of said MEKK to be phosphorylated or to phosphorylate a substrate such as MAP kinase or other substrate disclosed in the Examples such that apoptosis of the cell is regulated, does not reasonably provide enablement for other MEKKs or agents that stimulate MEKK activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses MEKK of SEQ ID NOs: 2 and 4 encoded by the nucleic acid of SEQ ID NOs: 1 and 3 respectively. Specification also discloses cell death resulting from MEKK expression required the kinase activity of the enzyme, page 101. The MEKK contains an NH₂-terminal regulatory domain that serves to regulate a second structural domain comprising a COOH-terminal protein kinase catalytic domain that is capable of phosphorylating an MKK protein, page 21. Although the specific fragment of MEKK1 that constitutes catalytic domain is not disclosed, the specification states the "preferred catalytic domain truncated MEKK" contains residues from about 409 to about 672 of SEQ ID NO:2 and about 1331 to about 1584 of SEQ ID NO:4, page 30. Further, the specific fragment of MEKK1 that constitutes the regulatory domain is not disclosed, the specification states the "preferred regulatory domain truncated

MEKK" contains residues from about 1 to about 408 of SEQ ID NO:2 and about 1 to about 1328 of SEQ ID NO:4, page 30. Specification also discloses cell death resulting from MEKK expression required the kinase activity of the enzyme, page 101. Figure 11 and Example 15 show MAP kinase activity was increased in cells expressing deletions of amino acids 211-215 of SEQ ID NO:2.

The ability to phosphorylate substrate is contained in the kinase catalytic domain of the protein of SEQ ID NO:2 and 4. The specific start and end of said domain is not disclosed. Further a protein comprising only residues of 409 to 672 of SEQ ID NO:2 and 1331 to 1584 of SEQ ID NO:4 has not been disclosed to regulate cell apoptosis. There is no disclosure showing that a complete lack of the regulatory domain will produce a functional protein. Although, the ability of regulatory region of MEKK to regulate the phosphorylation activity of the catalytic domain has been shown to be affected by a specific mutation in this regulatory region, other parts of the molecule are most likely needed to stabilize the catalytic domain for functionality. Further, the specification discloses no mutations in the catalytic domain that may produce functional protein. The claimed method can only be practiced if the catalytic domain has functional kinase activity, i.e. capable of phosphorylation. Proteins with 85% identity to SEQ ID NO:2 and 4, with mutations in the catalytic domain have not been shown to be functional. The specification nor prior art disclose any mutations that that may be produced in the catalytic domain of MEKK1 so as to produce a functional polypeptide capable of MAP kinase phosphorylation or phosphorylation of some other substrate that results in apoptosis of the cell. Therefore, while the skilled artisan, in light of the

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specification, would be able to use the MEKK1 disclosed in SEQ ID NO:2 and 4, or the polypeptide disclosed in Example 15, to regulate the MEKK protein to be phosphorylated or phosphorylate a substrate to regulate cell apoptosis, there is no disclosure in the specification or prior art that variants encompassed by only the name MEKK (name provides no structure and function association), variants with 85% identity with the regulatory domain of SEQ ID NO:2 or 4, variants with 85% identity with catalytic kinase domain of SEQ ID NO:2 or 4, or proteins that can be used to regulate activity of a MEKK protein in a cell such that apoptosis of cell is regulated. Also, it must be noted that no agents are disclosed that increase apoptosis of cells by increasing MEKK activity. Therefore applicants are not enabled for methods involving the use of agents to increase apoptosis by regulating MEKK activity. The scope of the claims, which encompass MEKK polypeptide variants without disclosure of a specific catalytic structure disclosed in SEQ ID NO:2 or 4 which is capable of functioning as a kinase, said MEKK having the ability to be phosphorylated or to phosphorylate MAP kinase or other substrate disclosed in the Examples, are not enabled by the disclosure. The disclosure does not teach how to make or identify such variants, or to use a commensurate number of the variants, which did not share all the catalytic properties encompassed by the peptide of SERQ ID NO:2 or 4. Due to the large quantity of experimentation necessary to identify/make the polypeptides used in instant method, the lack of direction/guidance presented in the specification regarding the mutation, production, identification and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of

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SEQ ID NO:2 and 4 are also encompassed by the claim), and the breadth of the claim which fail to recite the structural critical feature of the invention required for activity, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

Claim Rejection 35 USC § 112, 1st paragraph (Written Description)

10. Claims 53-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 53-58 are directed to method for regulating apoptosis of a cell comprising contacting the cell with an agent that regulates activity of MEKK protein in said cell such that apoptosis of the cell is regulated. The compound may inhibit the ability of a regulatory domain of MEKK protein to regulate the activity of a kinase domain of said MEKK. The MEKK protein may have kinase activity that is not regulated.

Claims 53-59 encompasses use of polypeptide/proteins variants of the protein identified as MEKK, said variants may be completely unrelated, structurally and functionally to use of the protein disclosed in SEQ ID NO:2 and 4. The name MEKK protein does not provide any structural limitations nor does it identify the critical feature of the invention. The name does not disclose the activity of the polypeptide.

The scope of the claims, which encompass MEKK polypeptides without disclosure of a specific kinase catalytic domain structure disclosed in SEQ ID NO:2 or 4 which is capable of functioning as a kinase, said MEKK having the ability to be phosphorylated or to phosphorylate MAP kinase or other substrate disclosed in the Examples, are not enabled by the disclosure. The common function of the protein of SEQ ID NO:2 and 4, which is based upon a common property or critical technical feature of the genus claimed, is not disclosed. The claims, as written, encompass use of proteins, which vary substantially in length and also in amino acid composition.

The specification discloses MEKK of SEQ ID NOs: 2 and 4 encoded by the nucleic acid of SEQ ID NOs: 1 and 3 respectively. Specification also discloses cell death resulting from MEKK expression required the kinase activity of the enzyme, page 101. The MEKK contains an NH₂-terminal regulatory domain that serves to regulate a

second structural domain comprising a COOH-terminal protein kinase catalytic domain that is capable of phosphorylating an MKK protein, page 21. The specific fragments of MEKK1 that constitute the catalytic domain and regulatory domain are not disclosed. Specification also discloses cell death resulting from MEKK expression required the kinase activity of the enzyme, page 101. Figure 11 and Example 15 show MAP kinase activity was increased in cells expressing deletions of amino acids 211-215 of SEQ ID NO:2.

The ability to phosphorylate substrate is contained in the kinase catalytic domain of the protein of SEQ ID NO:2 and 4. The specific start and end of said domain is not disclosed. The specification discloses no mutations in the catalytic domain that may produce functional protein. The claimed method can only be practiced if the catalytic domain has functional kinase activity, i.e. capable of phosphorylation. Proteins with 85% identity to SEQ ID NO:2 and 4, with mutations in the catalytic domain have not been shown to be functional. The specification nor prior art disclose any mutations that that may be produced in the catalytic domain of MEKK1 so as to produce a functional polypeptide capable of MAP kinase phosphorylation or phosphorylation of some other substrate that results in apoptosis of the cell. There is no disclosure in the specification or prior art that variants encompassed by only the name MEKK (name provides no structure and function association), variants with 85% identity with the regulatory domain of SEQ ID NO:2 or 4, variants with 85% identity with catalytic kinase domain of SEQ ID NO:2 or 4, or proteins encoded by nucleic acid molecule capable of hybridizing under unspecified stringent conditions with the nucleic acid consisting of SEQ ID NO:1

and 3 can be used to regulate activity of a MEKK protein in a cell such that apoptosis of cell is regulated.

The instant disclosure of the polypeptides of SEQ ID NO:2 and 4 does not adequately describe the scope of the use of the claimed genus, which encompasses a substantial variety of subgenera including proteins, variants of said proteins, chimeric constructs, fusion constructs which may contain polypeptides completely, unrelated structurally and functionally to the polypeptide of SEQ ID NO:2 and 4. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The claims fail to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides. There is no description of the conserved regions, which are critical to the structure, and function of the genus in the claims.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus as claimed, and because the genus is highly variant, the disclosure of specific polypeptide and nucleotide sequences is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe, enable and use the genus as broadly claimed. The skilled artisan cannot envision the detailed chemical

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structure of the encompassed proteins and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. It is acknowledged that the skill of the artisan in the molecular biology art is high. However, in the current instance, the critical special technical feature of the polypeptides or how the critical special technical feature encompassed by the genus claimed relates to function is not claimed. Because of the lack of guidance in the prior art and scope of the claims one skilled in the art could not predict if the variants claimed for use in instant invention have the same activity as the protein disclosed in SEQ ID NO:2 and 4, since no specific activity is disclosed, or if they contain the domain(s) of SEQ ID NO:2 and 4, containing the critical special technical feature of the invention.

The skilled artisan cannot envision the detailed chemical structure of the encompassed compounds and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does

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not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid or polypeptide is itself is required. See *Fibers v. Revel*, 25 USPQ d. 1601 at 1606 (CAFC 1993) and *Amen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Database PIR 78, Accession Number A39723, disclose a polypeptide sequence with 16.4% identity and 26.9% best local similarity with SEQ ID NO:2 . .

12. Applicant has stated in paper number 14, 4/15/03, the majority of the references listed on the enclosed PTO form 1449 have been previously cited or submitted to the Office in the prior application. Applicant has not disclosed which Application contains said references. Further Applicant has not disclosed which references were cited and which references were submitted. Applicant is advised to specifically disclose in which Application each reference was cited, or attach copies so that the Examiner may consider them.

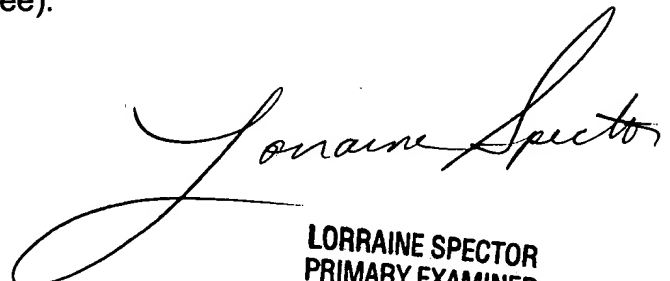
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
May 17, 2004



LORRAINE SPECTOR
PRIMARY EXAMINER